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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,754	01/30/2002	Jeffry B. Skiba	125827-1000	8210

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EXAMINER

ANDERSON, CATHARINE L

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

7/2/05

Office Action Summary	Application No. 10/060,754	Applicant(s) SKIBA ET AL.	
	Examiner C. Lynne Anderson	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 17-31 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 12 May 2005 have been fully considered but they are not persuasive.

In response to the applicant's argument that Kang discloses goggle rather than a mask, it is noted that a mask is defined as a cover or partial cover for the face (Merriam-Webster's Collegiate Dictionary, 10th Edition). The apparatus of Kang partially covers the face during use, and therefore fulfills the definition of a mask. Further, the instant invention, as shown in the figures, also only partially covers the face, and appears to cover no more of the face than the apparatus of Kang.

In response to the applicant's argument that the apparatus of Kang comprises additional features not required by the claimed invention, it is noted that the claims disclose an apparatus comprising certain features. Comprising is an open-ended, and therefore inclusive rather than exclusive, limitation. Kang discloses all structural limitations of the claim, and therefore the claim is anticipated by Kang, irrespective of additional features disclosed by Kang.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-7, 9, 12-13, 15, 17, 19-23, 25, and 28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Kang (5,807,357).

Kang discloses an apparatus for delivering medicine to tissues, as shown in figure 2, comprising a mask 10 to be worn around the eyes, the mask 10 comprising fog outlets (shown as holes in figure 3, but not numbered). An atomizer 20 atomizes medicine 90 into a fog to be discharged from the fog outlets.

With respect to claim 2, the atomizer 20 comprises an ultrasonic atomizer, as disclosed in column 2, lines 29-32.

With respect to claim 3, the atomizer 20 comprises a nozzle 11, as shown in figure 3.

With respect to claim 4, the atomizer 20 is a nebulizer, as disclosed in column 1, line 54.

With respect to claim 6, the atomizer 20 comprises a medication chamber 71, as shown in figure 2.

With respect to claim 7, a conduit 11 is in fluid communication with the atomizer 20 and fog outlets, as shown in figure 3.

With respect to claim 9, a propellant source 30 is in fluid communication with the atomizer, as shown in figure 3.

With respect to claim 12, a power supply 40 is connected to the atomizer 20.

With respect to claim 13, the power supply 40 comprises batteries, as disclosed in column 1, line 60.

With respect to claim 15, the apparatus comprises a mask 10 having a transparent face mask 12 to be worn around the eyes, fog outlets (shown as holes in figure 3, but not numbered), an atomizer 20 to atomize medicine 90 into a fog, a medication chamber 71, a power supply 40, a propellant source 30, and a conduit 11.

With respect to claim 17, the power supply 40 comprises a battery, as disclosed in column 1, line 60.

With respect to claims 19 and 20, the method of administering medications to the eyes by nebulizing a medication to form a fog and contacting the fog with the eyes is disclosed in column 2, lines 27-36.

With respect to claim 21, the apparatus comprises a device 10 comprising fog outlets (shown as holes in figure 3, but not numbered), and an atomizer 20 in fluid communication with the fog outlets.

With respect to claim 22, the atomizer 20 is a nebulizer, as disclosed in column 1, line 54.

With respect to claim 23, a conduit 11 is in fluid communication with the fog outlets, as shown in figure 3.

With respect to claim 25, a propellant source 30 is in fluid communication with the atomizer 20.

With respect to claim 28, a power supply 40 is connected to the atomizer 20.

With respect to claim 29, the power supply 40 comprises batteries, as disclosed in column 1, line 60.

With respect to claims 30 and 31, Kang discloses a method of providing the mask described above and atomizing fluid into a fog, as disclosed in column 2, lines 27-36.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kang (5,807,357) as applied to claim 1 above.

Kang discloses all aspects of the claimed invention with the exception of the atomizer being a stirrer. Stirrers are well-known in the art as being suitable atomizers comparable to nebulizers. It would therefore be obvious to one of ordinary skill in the art at the time of invention to make the apparatus of Kang with a stirrer.

Claims 8, 18, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang (5,807,357) as applied to claims 1, 15, and 21 above, and further in view of Dykstra et al. (5,935,982).

Kang discloses all aspects of the claimed invention but remains silent as to the size of the liquid droplets of the fog. Dykstra discloses administering a medicine to the eyes, the medicine being in the form of liquid droplets having a size of less than 5 microns, as described in column 12, lines 13-15 and 36-37. It would therefore be obvious to one of ordinary skill in the art at the time of invention to make the droplets of Kang less than 5 microns, since Kang teaches less than 5 microns as a suitable size for medicine being delivered to the eyes.

Claims 10-11 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang (5,807,357) as applied to claims 1 and 21 above.

Kang discloses all aspects of the claimed invention with the exception of the propellant source comprising a compressed gas canister or a pump. Kang discloses the propellant source is a fan, as described in column 2, lines 33-35. It is well-known in the art that a compressed gas canister or pump perform a comparable function to a fan, and it would therefore be obvious to one of ordinary skill in the art at the time of invention to construct the apparatus of Kang with a compressed gas canister or a pump.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kang (5,807,357).

Kang discloses all aspects of the claimed invention with the exception of the power source being a wall outlet. It is well-known in the art that a wall outlet is a comparable power source to a battery, and it would therefore be obvious to one of ordinary skill in the art at the time of invention to construct the apparatus of Kang with the power source being a wall outlet.

Allowable Subject Matter

Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The prior art of record fails to disclose or suggest the use of flexible conduits for delivering a medicament from an atomizer to the eye of a patient, the atomizer comprising part of a transparent face mask. The closest prior art of record, Kang, discloses a conduit 11 for delivery of the medicament, as shown in figure 3, that is formed from and defined by the walls of the mask, which is static. Providing a flexible conduit would therefore go against the teaching of Kang.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Lynne Anderson whose telephone number is (571) 272-4932. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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CWA
cla
July 29, 2005

TATYANA ZALUKAEVA
PRIMARY EXAMINER
Tatyana